

Integrating Health Outcomes and Medical Publication Planning

A Real World Example

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Disclosure

Jeff and Mehul are employees of sanofi-aventis, U.S., Inc.

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Traditional Approach

- Health Outcomes Team
 - Demonstrate product value to key customers through customer-centric health economics and outcomes research
- Publications Team
 - Disseminate key data and findings to targeted customers (Providers, Payers, etc.) via abstracts/posters, manuscripts

Health Outcomes Team

Health Outcomes Team

- Outcome Research
- Health Economic Models
- Database / EMR Studies
- CER/Systematic Reviews
- Meta-analysis
- Phase III / IV Clinical Trials
- PRO studies
- Patient Registries
- Data Mining
- Data Modeling

- Evidence generated to support Medical Team's strategies and drivers
- Worked with Medical team in order to complement and support the clinical story
- Goal of research was to answer scientific questions and disseminate findings to audiences externally

Publications Team

- Developed and maintained the publications plan for Medical / Clinical Trial program
- Worked on all phases of product life-cycle
 - Pre-clinical / Disease-level
 - Clinical trial Pre-Launch
 - Clinical trial Post-Launch

Publications Team

- ❑ Primary publications for clinical trial program
 - Phase I-IV Clinical Trials
 - Drug-Drug interaction
 - Pharmacokinetic studies
- ❑ Disease-management publications
- ❑ Secondary / Review manuscripts
- ❑ Health Outcomes and Pharmacoeconomic manuscripts

Interaction Between HO & Pubs Teams

- Limited knowledge-sharing among members of the same therapeutic area
 - Partnership began in final phases of HO studies
 - Limited integration of HO pubs into the overall pubs plan
- Colleagues worked as a team, though collaboration was suboptimal
 - Insufficient alignment impacted Value Communication to physicians, payers, and patients
 - HO pubs supplemented to overall Pubs Plan

Organizational Impact

- Health Outcomes and Publications Silos lead to a fragmented Publications Plan
 - Medical and Health Outcomes pubs plans not well-integrated
 - Health Outcomes evidence supporting clinical trial program not always incorporated efficiently
- Lack of strategic alignment impacted the organizational value of Health Outcomes research
- Synergistic opportunities for dissemination of key research were overlooked

Environmental Change

Benefits of Organizational Transformation

1. Consolidation of Scientific Publications

- **Functional alignment**
- **Harmonization of pubs** from ALL sources within the organization

Environmental Change

Benefits of Organizational Transformation

2. Revised publication processes

- **New SOPs**
- **Broader, more formalized process** for development and review

Environmental Change

Benefits of Organizational Transformation

3. Publications team reaches out to cross-functional teams

- **Exposure**
 - ✓ Information
 - ✓ Communication
 - ✓ Collaboration
- **New ways of working are meant to HELP, not HINDER**

Fruits of Our Labor

- **Collective discussion and solution development for common publishing issues**
 - **Appropriate authorship policies and practices**
 - Ensuring ICMJE criteria followed
 - **Ensuring highest quality submissions**
 - Incorporating congress/journal requirements in early development
 - **Harmonizing complementary efforts**
 - Clinical and health economic information presented together, as appropriate
 - **Compliance with Legal/Regulatory principles**



And so we began working more closely, consistently...

**...but there was still room for
improvement...**

Evolving with a Changing World

Value-Oriented Marketplace

Escalating Health Care Costs

Globalization

Drug Development Costs

Uninsured/Underinsured

Primary Care Shortage

Drug Safety Concerns

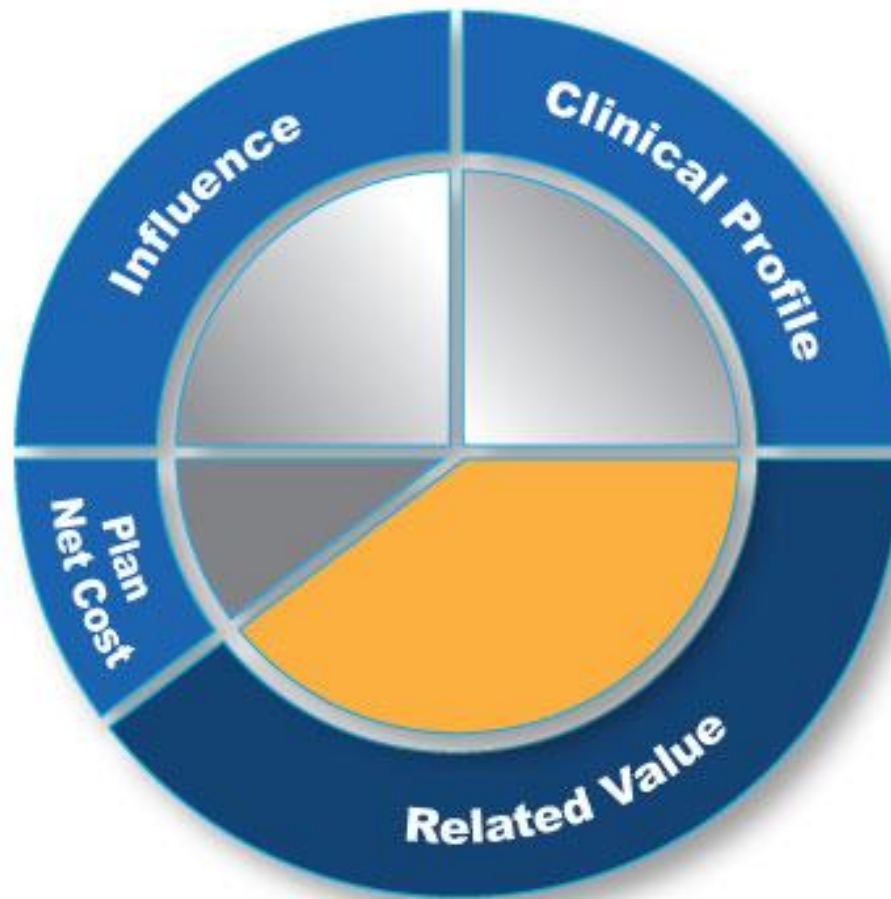
Aggressive Tx Guidelines

More Boomers (> 65 years)

Increased Generic Utilization

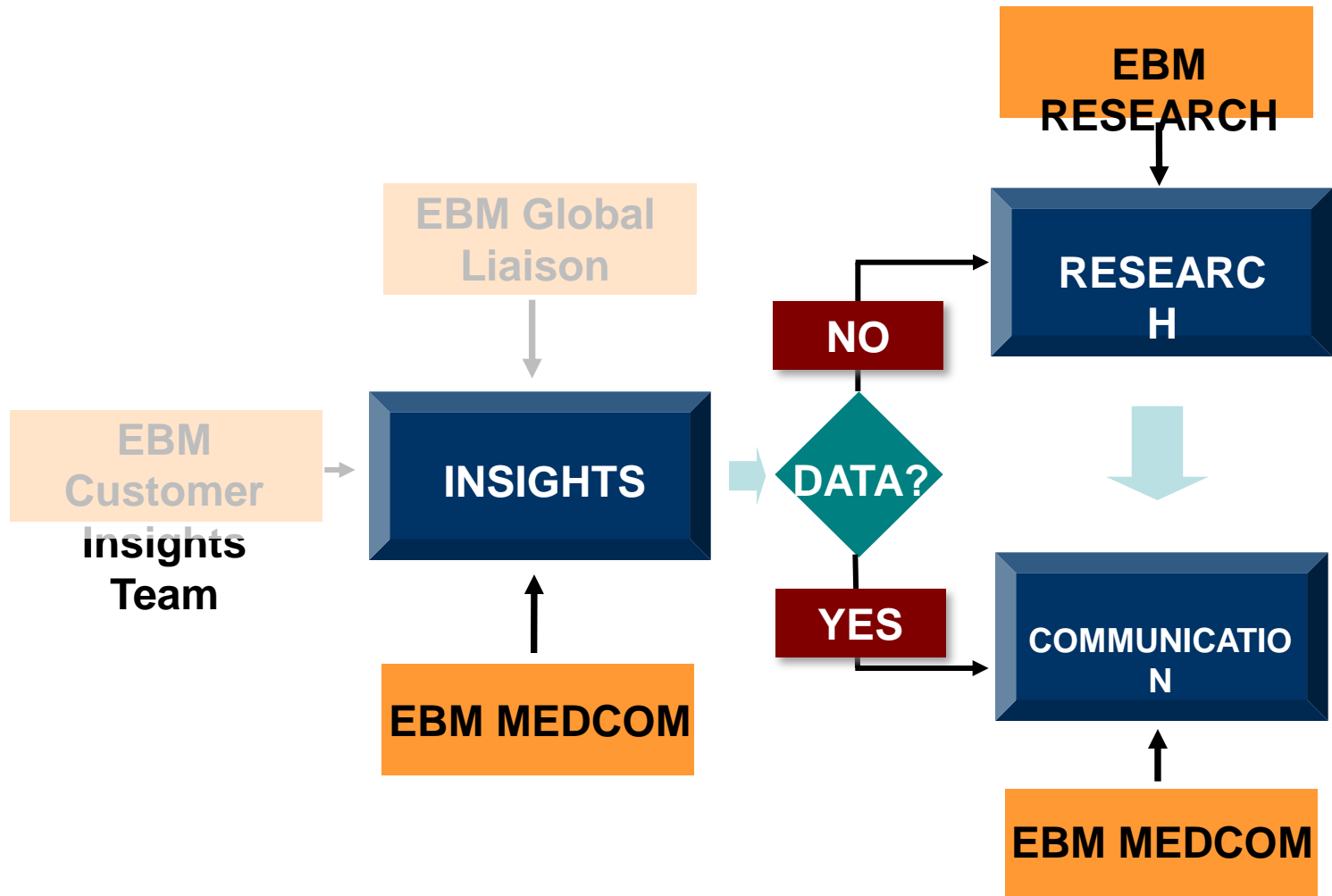
Need for greater access, quality, effectiveness

Focus on Value

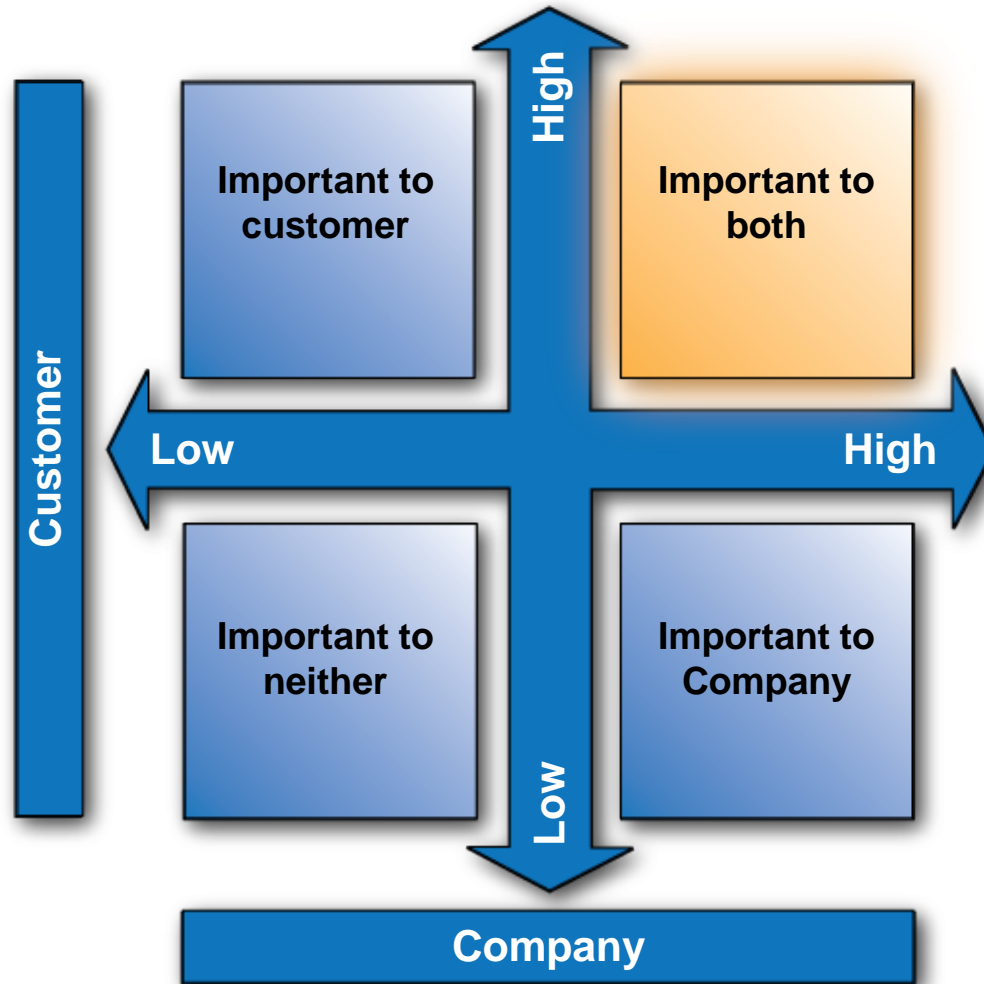


Transforming, Again!

“Align internal resources and customer needs with real-world experience and feedback”



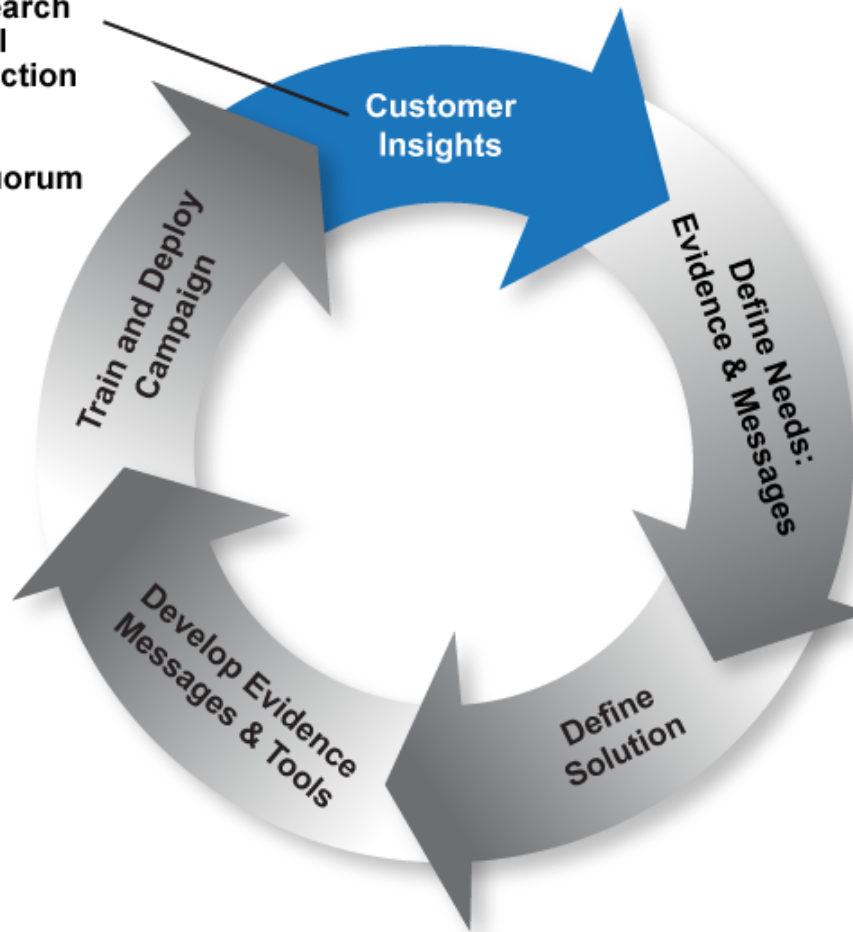
Partnerships, Listening, and *Solutions*



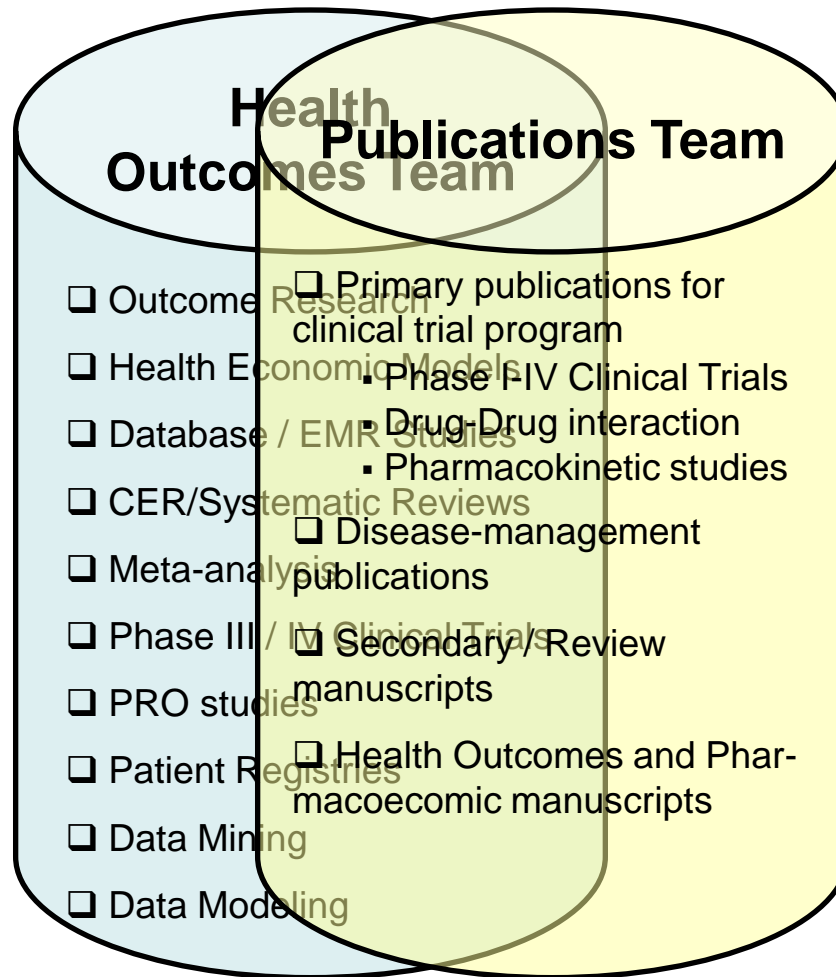
Integration: No Longer an Option!

Listen, Generate-Communicate Evidence, Evaluate Relevance

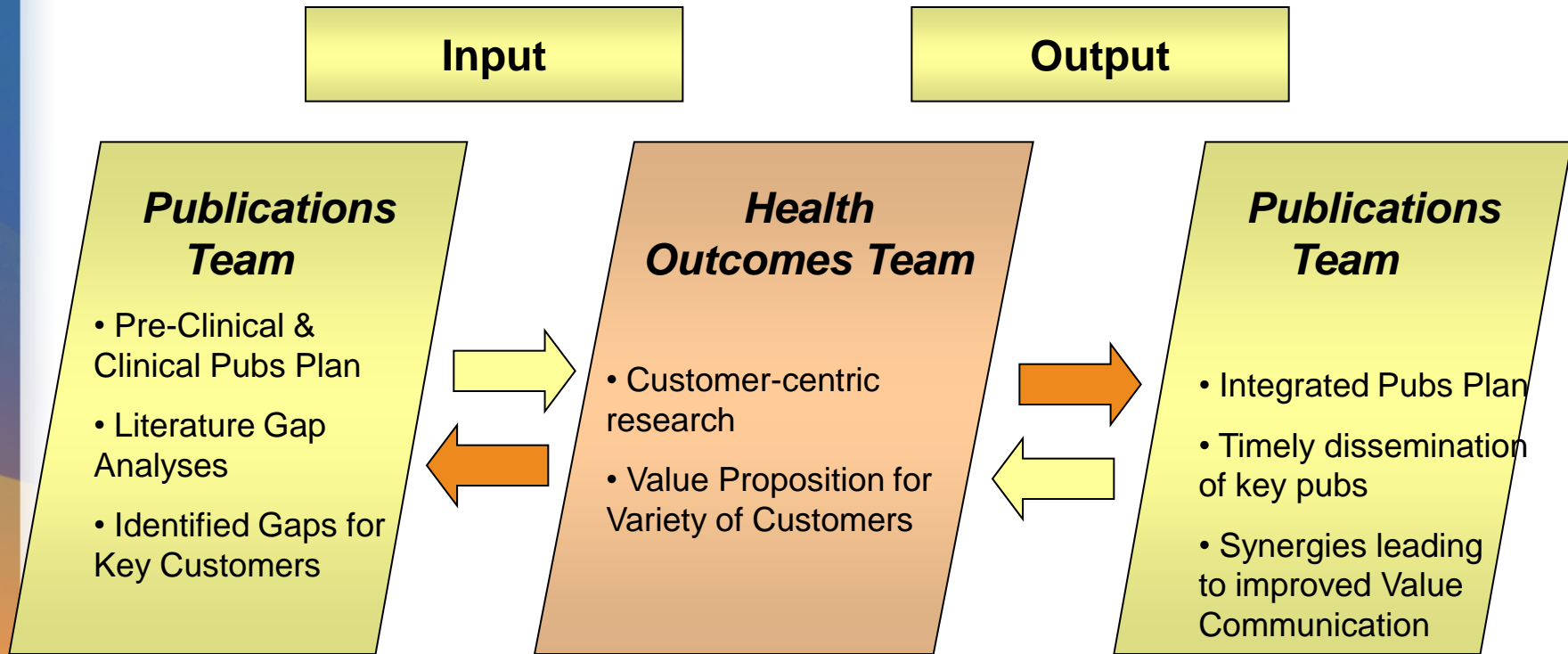
- Market Research
- Expert Panel
- Direct Interaction
- Media
- Literature
- Advisory Quorum



From Silos to Collaboration...



...to Synergistic Opportunities



Impact on Publication Plans

- **Strategic** dissemination of key publications
- Sequential and synergistic publications that develop a story flow
 - Disease-state publications
 - Clinical trial publications
 - Value-proposition publications
- Health Outcomes Publications that are complementary to the Pubs Plan rather than supplementary
- Overall value of all publications plan enhanced for internal and external customers

Organizational Impact of Integration

- Quality of Health Outcomes research and Publications Plan is enhanced
- Added Value of Publications and Health Outcomes efforts in overall organizational strategy (internally)
- Focused Medical communications (externally)
 - Targeting of journals enhanced
 - Audience segmentation for dissemination of messages refined
 - Improved efficiencies of publications

Summary & Recommendations

- We don't always have the luxury of organizational change!
- Reaching out can be difficult, but integration in the long run provides tangible added value
 - To internal stakeholders and to customers
 - Improved quality, efficiency, and cohesiveness
- Begin with taking a baseline on processes and standards
 - Educate colleagues on the need for change
- Start a pilot with the most 'flexible' existing teammates
- Seek/justify management support of added value and risk aversion
 - Build the case, present, convince, bring solution plan
 - Have the team help build the case and develop solutions



Thank you.